

REMARKS/ARGUMENTS

Claim 1 has been amended to recite an immunostimulant milk product which does not include live *Bifidobacteria*. Support for this amendment is found at page 5, lines 4-9. Claim 1 has also been amended to recite the step of “bringing and keeping said substrate into contact” to provide proper antecedent basis for “the bringing into contact” as recited in claim 3. Claim 5 has been amended to clarify that the *Bifidobacterium* culture comprises the *Bifidobacterium breve* strain deposited on May 31, 1999, under number I-2219 at the CNCM. Claims 14 and 15 have been withdrawn. Applicants respectfully submit that these claim amendments will place the application in condition for allowance and are proper under 37 CFR 1.116. Therefore, Applicants respectfully request entry of these amendments.

A. Rejections under 35 U.S.C. §112

Claim 3 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Office argues that “the bringing into contact” lacks sufficient antecedent basis. Accordingly, Applicants have amended independent claim 1 to recite the step of “bringing and keeping said substrate in contact with said culture.” In view of the current amendment to independent claim 1, Applicants submit that claim 3 now has proper antecedent basis and that this rejection has been overcome.

Claim 5 stands rejected under 35 U.S.C. §112, second paragraph, as being vague and indefinite for reciting “is used.” The Office argues that it is unclear as to what is being used and for what purpose. Accordingly, claim 5 has been amended to clarify that the *Bifidobacterium* culture comprises the *Bifidobacterium breve* strain deposited on May 31, 1999, under number I-2219 at the CNCM. In particular, the deposited strain is being used for the purposes set forth in independent claim 1. In view of the current amendment to claim 5, Applicants submit that this rejection has been overcome.

B. Rejections under 35 U.S.C. §102(b)

Claims 1-5 and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,187,321 to Mutai et al. (hereinafter “the ‘321 patent”). Claims 1-5 and 13 stand

rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,230,912 to Yajima et al. (hereinafter “the ‘912 patent”). Claims 1-5, 7-10 and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,091,117 to Mutai et al. (hereinafter “the ‘117 patent”). As currently amended, independent claim 1 recites an immunostimulant milk product which does not include live *Bifidobacteria*.

To establish an anticipation, a prior art reference must disclose the invention as set forth in the claim. Specifically, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. §2131 citing *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully submit that the ‘321 patent, the ‘912 patent, and the ‘117 patent each fail to disclose each and every element of the currently claimed invention. In particular, all three references cited as being anticipatory do not disclose an immunostimulant milk product which does not include live *Bifidobacteria*. Instead, the cited references disclose a milk product including live *Bifidobacteria*.

The ‘321 patent is directed to a method for producing foods containing at least two kinds of viable *bifidobacteria* by utilizing a mixed cultivation of oxygen-resistant mutant strains of *Bifidobacterium* with obligatory anaerobic *bifidobacteria*. According to the teachings of the ‘321 patent, industrial production of food containing *bifidobacteria* has not yet been made due to the difficulty in cultivation (column 1, lines 46-49). However, the inventors of the ‘321 patent successfully established a method for cultivating *Bifidobacterium* to provide food and drink containing *Bifidobacterium* at a low price (column 1, lines 50-53). Since no growth promoting agents are necessary, “fermented milk containing *Bifidobacterium* alone with no additives is obtained.” See column 2, lines 43-47. Furthermore, the ‘321 patent teaches that food and drink products containing more than one species of *Bifidobacterium* such that it provides products collectively excellent in physiological activity and taste is achieved (column 2, lines 11-25). Clearly, all food products disclosed by the ‘321 patent necessarily contain viable *bifidobacteria*.

Unlike the ‘321 patent, the products of the currently claimed invention are prepared under conditions which are unfavorable to fermentation by *bifidobacteria* and do not include live

Bifidobacteria as a result of the sterilizing and/or desiccating step. Consequently, the '321 patent does not anticipate independent claim 1 or any claims dependent thereon.

The '912 patent is generally directed to a method of producing milk-fermented food by inoculating a bifidobacteria and / or a lactic acid bacteria into and cultured in a culture medium composed mainly of milk. More specifically, the '912 patent teaches a method of producing milk-fermented food, wherein the fermenting period for producing the milk-fermented food which is fermented by bifidobacteria and/or lactic acid bacteria is shortened to (1) increase the numbers of live bacteria in the product, (2) increase the bacteria survival rate and (3) maintain bacteria numbers for a long period. See column 2, lines 50-55. Therefore, the '912 patent teaches a milk-fermented food wherein the survival rate of the bifidobacteria is improved so as to maintain the numbers of viable bacteria. See column 2, lines 59-61.

To the contrary, the products of the currently claimed invention are prepared under conditions which are unfavorable to fermentation by *bifidobacteria* and do not include viable *bifidobacteria* as a result of the sterilizing and/or desiccating step. Consequently, the '912 patent does not anticipate independent claim 1 or any claims dependent thereon.

The '117 patent, titled "Fermented Milk Product Containing Viable *Bifidobacteria*" is directed to a method for producing fermented milk containing viable bifidobacteria. The viable *bifidobacteria* containing milk is produced by "cultivating a variant of *bifidobacteria* in a milk medium, characterized in that the variant of bifidobacteria is acid-resistant and can be propagated under an aerobic condition in a pure milk medium which does not contain any growth-promoting substance." See Abstract. The '117 patent teaches that by using the variant *bifidobacteria* strain it has become possible to conduct the efficient cultivation which could not be carried out by using the conventional known bifidobacteria, and to produce food and drink containing the viable bifidobacteria. See column 4, lines 45-50.

Similar to the '321 and '912 patents, the '117 patent requires viable *bifidobacteria* in a food or milk product. Unlike the '117 patent, currently amended independent claim 1 recites immunostimulant milk products which are prepared under conditions which are unfavorable to fermentation by *bifidobacteria* and do not include live *Bifidobacteria*. Consequently, the '117 patent does not anticipate independent claim 1 or any claims dependent thereon.

Since the '321 patent, the '912 patent, and the '117 patent all require a product including live *Bifidobacteria*, these references simply fail to disclose an immunostimulant milk product which does not include live *Bifidobacteria*. Accordingly, each reference fails to disclose each and every element of the currently claimed invention. Therefore, Applicants submit that the rejections under 35 U.S.C. §102(b) have been overcome.

C. Rejections under 35 U.S.C. §103(a)

Claims 1 and 13 stand rejected under 35 U.S.C. §103(a) as being obvious over the '117 patent in view of U.S. Patent No. 6,034,130 to Wang et al. (hereinafter "the '130 patent") and / or U.S. Patent No. 4,753,926 to Lucas et al. (hereinafter "the '926 patent").

To establish a *prima facie* case of obviousness there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine or modify the reference teachings. Additionally, the cited references must teach or suggest each and every claim limitation. Furthermore, the teaching or suggestion must be found in the prior art, not in Applicants' disclosure. Applicants submit that the Office has not proven a *prima facie* case of obviousness because (1) all of the cited references fail to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria* and (2) the necessary motivation for combining the cited references or modifying the teachings of the '117 patent as suggested by the Office are lacking.

As discussed above, the '117 patent is directed to a method for producing fermented milk containing viable bifidobacteria. The '117 patent provides that *Bifidobacteria* have been known to provide various physiological properties such as (a) suppression of putrefactive bacteria; (b) inhibition of production of toxic amines; (c) promotion of digestion of human milk casein by the action of phosphoprotein phosphatase; and (d) growth inhibition of pathogenic bacteria in conjunction with lowering the pH in the intestines by production of lactic acid, acetic acid, formic acid and the like. See column 1, lines 10-20. The '117 patent also states that "an infant who is bottle-fed has very few intestinal *bifidobacteria* which, as mentioned above, have various effects in keeping the intestines healthy. This is considered to be the reason why a bottle-fed infant is more susceptible to intestinal diseases in comparison with a breast-fed infant. Therefore,

for the purposes of converting the intestinal flora of a bottle-fed infant to those similar to that of a breast-fed infant, modified powdered milk for infants containing *bifidobacteria* has tentatively been prepared as a substitute for human milk.” See column 1, lines 21-32. Accordingly, the ‘117 patent teaches using a variant *bifidobacteria* strain to conduct the efficient cultivation which could not be carried out by using the conventional known *bifidobacteria*, and to produce food and drink containing the viable *bifidobacteria*. See column 4, lines 45-50. Furthermore, the ‘117 patent teaches that the cultured product, according to the ‘117 patent, contains “a large number of viable *bifidobacteria* having excellent survivability and their milk metabolites, particularly an organic acid mixture predominantly comprising acetic acid and lactic acid, can be utilized as a food as it is or as an additive to food and drinks. ... For example, the cultured product and its dried material can be used in combination with food and drinks having a pH of 4 - 7, which are not heated to the lethal temperature of the *bifidobacteria*.” See column 5, lines 18-35.

The teachings of the ‘117 patent clearly demonstrate that all products contemplated must include live *bifidobacteria* to satisfy the need of maintaining the health of intestines for bottle fed infants and to reduce their susceptibility to intestinal diseases in comparison with a breast-fed infant. This is also evident by the teaching that the cultured product is not to be exposed to conditions or used in a manner wherein the live *bifidobacteria* may be destroyed. As discussed both here and above, the ‘117 patent does not teach or suggest an immunostimulant milk product which does not include live *bifidobacteria*. To the contrary, the ‘117 patent teaches a milk product that must include live *bifidobacteria*. Thus, the ‘117 patent actually teaches away from the currently claimed invention by requiring products including live *bifidobacteria*.

Since, the ‘117 patent does not teach a sterilized milk product, as acknowledged by the Office, the Office attempts to cure this deficiency with the teachings of the ‘130 and the ‘926 patents. The Office cites the ‘130 and the ‘926 patents for teaching sterilized baby food. Alternatively, the Office relies on the ‘130 and the ‘926 patents as support that “one of ordinary skill in the art would have been motivated by routine practice to sterilize the baby food disclosed by Mutai (the ‘117 patent), since it was routinely practiced as evidence by the cited references.” See page 9 of the Office Action dated November 8, 2006.

The '130 patent is generally directed to dietetic lipids for infant formulas; wherein the lipid composition is close to that of human milk. More specifically, the '130 patent teaches a synthetic triacylglycerol (TAG) composition wherein the composition and structures are close to those of human milk. The compositions are prepared by using a synthesized process for incorporating polyunsaturated fatty acids (PUFAs) which do not cause significant destructive oxidation of the PUFAs. Accordingly, the '130 patent teaches a synthetic lipid composition in which the content and the distribution of the fatty acids mimic those of human milk fat. For instance, the '130 patent provides that the "invention also relates to an infant food containing proteins, where appropriate hydrolysed, carbohydrates, lipids and where appropriate vitamins and trace elements, characterized in that it contains, by weight of dry matter, 15 to 35% of lipids of which 50 to 100% consist of the above lipid composition. Such an infant food can be prepared in liquid or powdered form with incorporation of the above lipid composition, by wet mixing of the various constituents, followed by sterilization or pasteurization and aseptic packaging in the case of a liquid product or by drying, for example by spray-drying or by dry mixing in the case of a powder." See column 4, lines 15-27.

The '130 patent simply does not teach or suggest a milk product, much less an immunostimulant milk product which does not include live *bifidobacteria*. The teachings of the '130 patent clearly demonstrate that this patent is neither directed nor concerned with providing an immunostimulant milk product. Instead, the '130 patent is concerned with formulating lipid compositions that merely mimic the content and distribution of fatty acids of human milk fat. Since both the '117 patent and the '130 patent fail to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria*, any combination of these references also fails to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria*.

The '926 patent is directed to foods, specifically an artificial milk product, for use in feeding low birth-weight infants or preterm infants. The '926 patent is concerned with providing infant food products that satisfy the unique nutritional requirements of low birth-weight infants. The '926 patent teaches that the nutritional requirements of such infants is not satisfied by feeding the infants with human breast milk. See column 1, lines 16-19. Accordingly, the

artificial milk products of the '926 patent contain a relatively high level of vitamin B₂, vitamin B₆, vitamin C, vitamin D, vitamin E, folic acid, copper and zinc. The '926 patent teaches that one particularly valuable food is an artificial milk that provides the requisite nutrients for infants with such unique nutritional requirements. See column 8, lines 5-8. The products according to the '926 patent may also be provided in a ready-to-use, sterilized liquid form. See column 8, lines 40-41.

Similar to the '130 patent, the '932 patent also does not teach or suggest a milk product, much less an immunostimulant milk product which does not include live *bifidobacteria*. The teachings of the '932 patent demonstrate that this patent is neither directed nor concerned with providing an immunostimulant milk product. Instead, the '932 patent is concerned with formulating artificial milk products that include specified nutritional constituents such as various vitamins at specified concentrations. Since both the '117 patent and the '932 patent fail to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria*, any combination of these references also fails to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria*.

Any combination of the '117 patent with the '130 patent and/or the '932 patent, in the manner proposed by the Office, would result in a sterilized milk product wherein the live *bifidobacteria* are destroyed in the sterilization process. However, the '117 patent specifically teaches the need for including and maintaining live *bifidobacteria* in the milk products contemplated. Furthermore, the '117 patent explicitly teaches away from subjecting the milk food product containing live *bifidobacteria* from additional processing, conditions or uses that would result in the destruction of the live *bifidobacteria*. See column 5, lines 34-35. Accordingly, the product that results from the combination of the '117 patent with either the '130 and / or the '932 patent is antithetical to the explicit advantages and motivation for formulating a milk product including live *bifidobacteria* having excellent survivability as taught by the '117 patent. After reading the '117 patent, one skilled in the art would be incited to steer away from sterilizing the milk product or any other function that might result in the destruction of the live *bifidobacteria*. In fact, if the milk product of the '117 patent was sterilized, as suggested by the Office, the product of the '117 patent would no longer be fit for its intended purpose of providing

viable *bifidobacteria* to the intestines of infants. Therefore, the '117 patent teaches away from such a combination, and the '117 patent in view of the '130 patent and/or '932 patent fails to provide a *prima facie* case of obviousness that is necessary for a proper rejection of claims 1 and 13.

Similarly, one skilled in the art would not be motivated by knowledge generally available in the art to sterilize the milk product of the '117 patent since this would render the milk product of the '117 patent unfit for its intended purpose. Accordingly the necessary motivation for modifying the teachings of the '117 patent to result in a sterilized milk product is *per se* lacking.

Since the '117, the '130 and the '932 patents all fail to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria*, any combination of the cited references also fails to teach or suggest an immunostimulant milk product which does not include live *Bifidobacteria*. Accordingly, the '117 patent alone or in any combination with the cited references does not teach or suggest each and every element of the currently claimed invention. Furthermore, the necessary motivation for combining the '117 patent with the '130 and / or the '932 patent is lacking since (1) the '117 patent teaches away from such a combination and (2) such a combination would render the milk product of the '117 patent unfit for its intended purpose. Likewise, one skilled in the art would not be motivated by knowledge generally available in the art to sterilize the milk product of the '117 patent since this would render the milk product of the '117 patent unfit for its intended purpose. Consequently, the necessary motivation for modifying or combining the reference teachings as proposed by the Office is lacking. For these reasons, Applicants submit that the rejections under 35 U.S.C. §103(a) have been overcome.

D. Conclusion

In view of the amendments and remarks made above, Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required,

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beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John E. Johnson, III', with a stylized flourish at the end.

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